

Applicants: John H. HEALEY and Gene R. DIRESTA  
Serial No.: 09/890,116  
Filed : November 20, 2001  
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REMARKS

Claim Status

Claims 77-115, 117, and 122-125 are pending in the application.

Rejection Under 35 U.S.C. §102/103(b)

Claims 77-115, 117, and 122-125 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as being unpatentable over WO 96/39107 (Merck Co.) and Sabokbar et al. (Ann. Rheum. Dis. 57:618 (1998)), and further in view of Remington's Pharmaceutical Sciences, 15<sup>th</sup> Edition, 1975, pages 1569-1570. The rejection is respectfully traversed.

The Examiner contends that the claims are drawn to a composition comprising a monomeric bone cement component and a polymeric bone cement component and an anti-resorptive agent component to prevent loosening of the polymerized bone cement matrix from a living bone to which it is attached.

The Examiner contends that Sabokbar et al. teach a polymethylmethacrylate (PMMA) bone cement, mixed with the bisphosphonate, etidronate, to inhibit bone resorption. Merck and Co. teach the addition of further bisphosphonates to the cement, added to the polymeric base. The Examiner concludes that it would have been obvious to one of ordinary skill in the art at the time it was made to add additional bisphosphonates as cited in Merck and Co.

In response, Applicants submit that claims 77, 93, and 110-115 have been amended to recite the following limitations: "wherein

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the anti-resorptive agent is present in an amount that does not compromise the bone cement's chemical or mechanical properties".

Applicants submit that Sabokbar et al. and Merck Co. do not teach or suggest the anti-resorptive agent is present in an amount that does not compromise the bone cement's chemical or mechanical properties as claimed herein. The present specification teaches that one advantage of the present composition is that satisfactory biomechanical characteristics are maintained after incorporation of anti-resorptive agent (page 37, lines 7-13). In the last response to office action filed August 21, 2006, Applicant intended to support the above assertion by a figure presented as an exhibit. The figure was described and discussed in the last response to office action (see page 23-24, filed August 21, 2006); however, the exhibit/figure itself was inadvertently left out of the paper filed to the patent office.

Applicants submit herein the same figure in two (2) Declarations under 37 C.F.R. §1.132 attached hereto as **EXHIBIT 1** and **EXHIBIT 2**. As indicated above, the data presented by the figure was described and discussed in the last response, but the figure itself was inadvertently left out of the paper filed to the USPTO. Hence, Applicants respectfully request that the Examiner would consider this as a reason why the Declarations were not presented earlier, and enter and consider the Declarations in this response.

As shown in Figure 1 of the Declarations presented herein, the bone cement composition of the present invention (designated as

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MSKCC) exhibits the same mechanical strength as compared to bone cement without any addition of anti-resorptive agent (designated as Drug Free SIMPLEX™). In contrast, the composition of Merck Co. (designated as MERCK and formulated according to WO 96/39107) has significantly decreased mechanical strength as compared to bone cement that does not contain anti-resorptive agent (comparing MERCK vs Drug Free SIMPLEX™). Hence, the addition of anti-resorptive agent according to WO 96/39107 (Merck Co.) actually compromises the performance of the bone cement.

Applicants submit that the Examiner has not provided any evidence that indicates Sabokbar et al. or Merck Co. teach or suggest addition of anti-resorptive agent would not compromise the bone cement's chemical or mechanical properties as claimed herein. Since neither Sabokbar et al. nor Merck Co. teaches or suggests the limitation listed above, neither Sabokbar et al. nor Merck Co. anticipates the present invention. Similarly, the combination of Sabokbar et al. and Merck Co. does not render the present invention obvious because the cited references taken together do not teach or suggest each and every limitation recited herein.

In view of the above remarks, Applicants respectfully request that the rejection of claims 77-115, 117, and 122-125 under 35 U.S.C. §102(b) or 35 U.S.C. §103(a) be withdrawn.

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CONCLUSION

Applicants respectfully maintain that all the grounds of rejections raised in the March 9, 2007 Final Office Action have been addressed and earnestly urge the Examiner to render favorable action for the claimed invention.

If a telephone interview would be of assistance in advancing the prosecution of the subject application, Applicants' undersigned attorney invites the Examiner to telephone him at the number provided below. If any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 50-1891.

Respectfully submitted,

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